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June 23, 2022

BY ECF

Honorable Jessica S. Allen, U.S.M.J.
United States District Court for the District of New Jersey
Martin Luther King Jr. Bldg. & U.S. Courthouse
50 Walnut Street
Newark, New Jersey 07102

Re: ***Mylan Pharms. Inc. v. Teva Pharms. Indus. Ltd., et al.*,**
Civil Action No. 2:21-13087 (JXN) (JSA)

Dear Judge Allen:

Mylan Pharmaceuticals Inc. ("Plaintiff") and Teva Pharmaceuticals Industries Ltd., Teva Pharmaceuticals, Inc., Teva Neuroscience, Inc., and Teva Sales & Marketing ("Defendants"), collectively ("the Parties"), submit this joint status letter in accordance with the accordance with the Court's June 1, 2022 Order (ECF No. 68).

Pursuant to the Order, the Parties have continued to exchange drafts of the ESI Protocol and are at agreement on all substantive provisions with the exception of the scope of disclosures regarding Technology Assisted Review ("TAR").

Teva's Position Regarding TAR

During the Parties' meet and confer process, Mylan has reserved the right to request a review of a statistically significant sample of non-responsive documents, citing *In re Valsartan, Losartan, & Irbesartan Prods. Liab. Litig.*, 2020 U.S. Dist. LEXIS 225666 (D.N.J. Dec. 2, 2020). However, in *Valsartan*, the parties disputed whether the Court-ordered protocol was followed with respect to certain TAR disclosures following the parties' productions and negotiation of search terms.

Here, productions have yet to begin and there have been no TAR disclosures made to raise concern. Moreover, as a general matter, a party is only entitled to documents that are responsive to the claims and defenses in the case, and Mylan has no basis to request or seek review of non-responsive materials for any purpose. In fact, the Parties have already agreed to withhold non-responsive documents in otherwise responsive families.

Mylan's Position Regarding TAR

As Teva notes, Mylan reserved its rights to review a statistically significant sample of non-responsive documents. Mylan's position is that this serves a necessary backstop to ensure the TAR process is faithfully and accurately executed. The review of a random sample of non-responsive documents is the typical method for ensuring the TAR software or training regimen is not errantly coding responsive documents as non-responsive. Indeed, the Court in *Valsartan* approved of the use of a similar validation provision granting plaintiffs the right to review 5000 alleged non-responsive documents to ensure compliance with the TAR protocol. *Id*. at *71. As the Court explained, "Teva's insistence that it is unheard of for alleged non-responsive or irrelevant documents to be produced either by court order or by agreement is not correct." *Id*. Mylan maintains that this reservation of rights is more than reasonable and appropriate as a TAR validation measure.

To the extent the issue regarding TAR disclosure has been resolved by the Court or by agreement, the Parties intend to finalize and execute the ESI Protocol on or before July 1, 2022 or shortly thereafter. Once the ESI Protocol agreed upon and executed, Teva's production of Phase 1 documents can begin, as identified in the Court's June 1 Order.

As requested by the Court, Mylan and Teva have reached an agreement on the categories of Qui Tam documents considered responsive for purposes of Phase 1 discovery in this action, as identified in the Joint Discovery Plan (ECF No. 47). The Parties established the following parameters to govern Teva's Phase 1 Qui Tam review.

The Parties agreed that the following principles govern Teva's Phase 1 Qui Tam review.

1. Anything that pertains solely to Azilect is non-responsive and does not need to be produced;

2. Documents that contain both relevant information and Azilect content should be produced but content that solely relates to Azilect can be redacted;

3. Documents that concern both Azilect and Copaxone but are not easily redactable (e.g., discussing the programs generally without specificity) should not be redacted and should be produced; and

4. The time frame for the documents begins on Jan. 1, 2008.

The Parties further agreed that anything that fits within the following categories is responsive for Purposes of Teva's Phase 1 review.

1. Consideration given to the prescribers (e.g., trips, cash, anything that could be consideration);

2. Documents relating to the speaker programs, including description, strategy, analysis, tracking, valuation, or efficacy (e.g., quantities, payments, metrics, ensuring prescriber loyalty);

3. Documents relating to the prescribers, including identification of the prescribers, communications with or about the prescribers, strategy, analysis, tracking, valuation, or efficacy (e.g., why the doctors were chosen, the rate at which doctors were prescribing Copaxone, etc.);

4. Anything discussing competition (e.g., effects of generic competition and competition generally); potential carve-out to the extent document expressly relates only to competition with another branded drug; or

5. Anything that connects the speaker programs to the DAW campaign.

Teva does not intend to object to the categories identified but reserves its right to raise any issues Teva encounters once the database of Qui Tam materials is restored.

As discussed earlier, once the ESI Protocol is finalized, Teva will be in a position to begin its rolling Phase 1 productions.

The Parties look forward to speaking with Your Honor during our status conference scheduled for June 28, 2022.

Respectfully submitted,

/s Arnold B. Calmann

Arnold B. Calmann

cc: Counsel of Record (by ECF & email)